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10/792,273	03/04/2004	Ruey J. Yu	BMR-008	4235

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/792,273	YU ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 31-57* is/are pending in the application.

4a) Of the above claim(s) *5-28 and 35-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,29,31-34,56-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-29 and 31-57 are presented for examination.

Applicant's Amendment filed August 14, 2007 has been received and entered into the present application.

Claims 1-29 and 31-57 are pending. Claims 1-4, 29, 31-34 and 56-57 are under examination and claims 5-28 and 35-55 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 56 and 57 are newly added and claims 4, 7-8, 10, 12, 16, 25 and 33-34 are amended.

Applicant's arguments, filed August 14, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Present claim 33 is now amended to specifically recite the units of the molecular weight of the hydroxyacid component of the molecular complex, i.e., that the molecular weight of the hydroxyacid is within the range of from about 50 g/mole to about 1000 g/mole. Present claim 34 is now amended to also

specifically recite the units of the molecular weight of the hydroxyacid component of the molecular complex, i.e., that the molecular weight of the hydroxyacid is within the range of from about 70 g/mole to about 700 g/mole.

In particular, the specification and claims as originally filed fail to provide adequate written description for the particular unit of molecular weight now claimed (i.e., grams per mole; claims 33-34).

MPEP §2163 states, "The issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not convention in the art or known to one of ordinary skill in the art...The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))...Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was

in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Regarding Applicant's newly added limitation of the unit of molecular weight of the hydroxyacid (claims 33-34), Applicant fails to direct the Examiner to the specific portion of the specification or claims as originally filed that provides adequate written support to now specifically claim that the molecular weight is measured in grams per mole.

However, the Examiner has carefully considered the specification and claims as originally filed for written support for this newly amended claim limitation. Relevant disclosure was found at, for example, page 22, para.[0055], which states:

"Because the molecular complex should be effective in permitting the release of the drug through the skin, it is preferred that the molecular weight of the hydroxyacid, or polyhydroxyacid, or related acid, or lactone form thereof be within the range of from about 50 to about 1000. It is more preferred that the molecular weight be within the range of from about 60 to about 700, and most preferred within the range of from about 70 to about 500."

While such teachings have been fully and carefully considered, it is noted that such disclosure fails to be supportive of the concept of limiting the disclosed molecular weights to gram per mole amounts. The disclosure of numerical molecular weights in the absence of any units ascribed to such molecular weights is not adequate written support to now narrow the claims to read specifically upon the disclosed numerical molecular weights as gram per mole amounts. This is a narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear, therefore, that Applicant was not in possession of the concept of the use of molecular weights of from about 50-1000 grams per mole or 70-700 grams per mole, since both the claims and disclosure as originally filed conspicuously failed to set forth any units for the disclosed molecular weights.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of molecular weights of the hydroxyacid used in the molecular complex of from about 50-1000 or 70-700 grams per mole (claims 33-34).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 57 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Newly added claim 57 is directed to a composition comprising a molecular complex formed between an alkaline pharmaceutical drug and at least one of a hydroxyacid, polyhydroxyacid, related acid, and lactone, wherein said molecular complex is formed by dissolving the alkaline pharmaceutical drug and an alkali in a suitable reaction medium to form a free base of the pharmaceutical drug, optionally separating the free base of the pharmaceutical drug from the reaction medium, and adding at least one of a hydroxyacid, a polyhydroxyacid, a related acid, or lactones thereof to the free base in a suitable reaction medium to form a molecular complex.

In particular, the term "suitable" in the phrase "suitable reaction medium" fails to clearly identify the reaction medium(s) tolerated by the claim because the claim fails to clearly, precisely or deliberately

set forth what would constitute a "suitable" reaction medium versus a non-suitable reaction medium. In other words, the properties and/or characteristics necessary to make the reaction medium "suitable" for use in the claimed process steps for forming the molecular complex are not so clearly defined as to indicate to one of ordinary skill in the art at the time of the invention the metes and bounds of the genus of "suitable reaction medium" intended by the claim. Furthermore, it is unclear what, exactly, is "suitable" about the reaction medium: should it be "suitable" for pharmaceutical use"? Or "suitable" for dissolving the alkaline pharmaceutical drug? Or "suitable" for forming the claimed complex? The nature of the term "suitable" is clearly open to subjective interpretation absent any indication in the claims (or even in the specification) as to what would, in fact, constitute said "suitable reaction medium". Such subjective interpretations are inconsistent with the tenor and express requirements of 35 U.S.C. 112, second paragraph.

For these reasons, the claims fails to meet the requirements under 35 U.S.C. 112, second paragraph, and is, thus, properly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 29, 31-34 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willcox et al. (U.S. Patent No. 5,863,544; 1999) in view of STN Registry File Registry No. 79-14-1 ("Glycolic Acid"), each already of record, and further in view of newly cited STN Registry File Registry No. 91161-71-6 ("Terbinafine), cited to show a fact due to Applicant's newly added claim(s), for the reasons of record set forth at pages 6-9 of the previous Office Action dated May 16, 2007, of which said reasons are herein incorporated by reference.

Newly added claim 56 is properly included in the present rejection because present claim 56 is dependent from claim 1 and further defines that alkaline pharmaceutical drug as terbinafine, which is taught by Willcox et al. as the additional dermatologically active agent for use in the disclosed cosmetic/dermatological composition comprising hydroxyacids, such as the preferred compound glycolic acid (col.2, l.32-34; col.5, l.9-30).

Newly added claim 57 is also properly included in the present rejection because present claim 57 circumscribes a composition of a molecular complex formed between the same alkaline pharmaceutical drug (i.e., terbinafine) and hydroxyacid (i.e., glycolic acid) as encompassed by claim 1 *et seq*. Regarding the process steps recited in the claim for forming the molecular complex, Applicant is reminded that these limitations are process limitations and fail to materially or structurally limit the claimed complex as a whole. As directed by the MPEP at §2113, "Even though product-by-process claims are limited by and defined by the process, *determination of patentability is based on the product itself.* The patentability of a product does not depend on its method of production. If the product in the product-by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" (see *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985 and MPEP §2113).

In the instant case, though the cited references do not expressly teach the dissolution of the alkaline pharmaceutical drug and an alkali in a suitable reaction medium to form a free base of the pharmaceutical drug, optionally separating the free base of the pharmaceutical drug from the reaction medium and adding at least one of a hydroxyacid, a polyhydroxyacid, a related acid or lactones thereof to the free base in a suitable reaction medium to form a molecular complex, the reference clearly provides for a pharmaceutical composition comprising the same alkaline pharmaceutical drug (i.e., terbinafine) and the same hydroxyacid (i.e., glycolic acid). Applicant defines the claimed molecular complex in the following manner:

> "The expression 'molecular complex' as used throughout this description to define the formation of a molecular complex between an alkaline pharmaceutical drug and the hydroxyacid, or polyhydroxy acid, related acid, or lactone denotes a complex based on three attracting forces. These three attracting forces in increasing strength are: (a) dipolar/dipolar; (b) dipolar/ionic; and (c) ionic/ionic. The dipolar attracting forces are created between the hydroxy groups of: (i) the hydroxyacid or polyhydroxy acid or related acid, or lactone; and (ii) the amino, imino and/or guanido group of an alkaline drug due to unshared electrons of the oxygen and nitrogen atoms, and the hydrogen atoms through hydrogen bonds. The ionic attracting forces are created between the carboxyl group of the hydroxyacid or polyhydroxy acid, or related acid, or lactone on the one hand, and the protonated amino, imino or guanido group of an alkaline drug on the other hand." (p.8-9, para.[0023-0024])

The very teaching of the same alkaline pharmaceutical drug (i.e., terbinafine) and the same hydroxyacid (i.e., glycolic acid), which clearly contains a hydroxyl group as evidenced by previously cited STN Registry File Registry No. 79-14-1, mixed together for use in a single pharmaceutical composition will necessarily result in the claimed molecular complex because the hydroxyl group of the glycolic acid (i.e., the hydroxyacid) contains unshared electrons on the oxygen atom of the hydroxyl group, which will form dipolar forces with the unshared electrons on the nitrogen atom of the terbinafine compound (the presence of unshared electrons are necessarily implied by the fact that the nitrogen is bonded to only three other substituents; see STN Registry File Registry No. 91161-71-6, cited to show a fact). Accordingly, the presence of such dipolar attractive forces clearly meets Applicant's claimed molecular complex, absent factual evidence to the contrary and/or absent any explanation or reasoning by Applicant as to why this purported complex would *not* occur in the disclosed composition of Willcox et

al.

In view of such reasons presented *supra*, Willcox et al. clearly meets the physical and structural elements presently claimed and, thus, properly renders the claimed composition obvious, regardless of the process by which it was produced. Absent any evidence on the record demonstrating a physical or structural comparison and difference between the claimed product and that of the prior art of Willcox et al., the cited reference clearly indicates that the prior art composition is the same, or substantially the same, in the physical elements and their structural arrangement such that this new process that Applicant now claims distinguishes the claimed product from that of the prior art does not, in fact, amount to a patentably distinct difference in the physical or structural nature of the claimed composition.

As stated in the MPEP at §2113, "Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, *the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.*" (emphasis added)

It has long been held that once a product has been fully disclosed in the prior art, future claims to that same product are precluded, even if that product is claimed as made by a new process. The presence of a process limitation in the product claim, where the product does not patentably distinguish over the prior art, cannot impart patentability to that same product. It is the product itself that must be patentably distinct from the product already known in the prior art. Though a product may be claimed in terms of the process of making it, the product must still be new in structural terms in order to meet the requirement for novelty. Although in some instances a claim may validly describe a new product with some reference to the method of production, a patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that the rejection "essentially alleges that Willcox anticipates the claims by disclosing every claim limitation" and further states "the rejection will be referred to as an alleged anticipation by Willcox as detailed by the Action" (Applicant's remarks, p.16). Applicant submits that anticipation by inherency requires that the prior art reference disclose each and every limitation of the claim and alleges that Willcox fails to inherently disclose a molecular complex that ***necessarily*** forms between the alkaline pharmaceutical drug and at least one agent selected from the group consisting of a hydroxyacid, a polyhydroxyacid, a related acid, a lactone form of these acids, and mixtures thereof. Applicant states, "the conditions present in Willcox's composition would not necessarily result in the formation of a molecular complex" (Applicant's remarks, p.18). Applicant alleges that Willcox discloses a composition comprising a water-in-oil emulsion containing hydroxyl acids, silicone bearing polyoxyalkylene substituents, coemulsifying compounds and optionally an active agent, but again asserts that the composition of the reference does not necessarily form a molecular complex.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

Initially, Applicant's subjective decision to consider the instant rejection an anticipation rejection fails to address the proper statutory basis of the rejection as previously set forth by the Examiner. The instant rejection was purposefully set forth as an obviousness rejection under 35 U.S.C. 103(a) and was ***not*** intended to be an anticipation rejection as alleged by Applicant. Accordingly, Applicant's decision to address the rejection under the standards of anticipation is most certainly not persuasive as it clearly fails to address the proper statutory basis of the rejection, i.e., the obviousness standard under 35 U.S.C. 103(a). However, in the interests of compact prosecution, Applicant's remarks will be addressed herein

as they apply to the 103 standard of obviousness that was relied upon the previous Office Action of May 16, 2007.

Regarding Applicant's allegation that anticipation by inherency requires that the prior art reference disclose each and every limitation of the claim and alleges that Willcox fails to inherently disclose a molecular complex that necessarily forms between the alkaline pharmaceutical drug (i.e., terbinafine) and the hydroxyacid (i.e., glycolic acid), Applicant is (1) again reminded that the instant rejection is an ***obviousness*** rejection, ***not*** an anticipation rejection and (2) reminded that a reference can still properly apply as prior art, even if the reference does not specifically disclose a particular property of the product, *if such a property is inherent to the product disclosed, though such a property may not have been recognized by the prior art.* Regardless, once the Examiner has demonstrated that the claimed product and that of the prior art product are substantially identical in structure or composition, a *prima facie* case of either anticipation ***or obviousness*** (in the instant case, obviousness) has been established and the burden shifts to Applicant to demonstrate that the products are not, in fact, the same. This shift of burden is clearly supported by the guidance set forth at MPEP §2112.01(I) and 2113, which states, "Where the claimed and prior art products are identical or substantially identical in structure of composition...a *prima facie* case of either anticipation or obviousness has been established...When the PTO shows a sound basis for believing that the products of the Applicant and the prior art are the same, the Applicant has the burden of showing that they are not." (MPEP §2112.01(I)).

In the instant case, Willcox et al. clearly meets each and every physical component of the claimed composition, thus, rendering the prior art product substantially identical to that of the product presently claimed. Though Willcox et al. does not expressly teach the "molecular complex" as presently claimed, Applicant is reminded that the instant specification defines such a "molecular complex" as resulting from attractive dipolar and/or ionic forces between the alkaline pharmaceutical drug and the hydroxyacid. However, the dipolar forces and/or ionic forces that form between the alkaline pharmaceutical drug and

the hydroxyacid are, absent factual evidence to the contrary, a direct result of the attraction between molecular dipoles caused by the presence of unshared electrons and the resultant electronegative atoms and electropositive atoms that are inherently present in the claimed components of the composition. Accordingly, the very presence of the two compounds in a single composition would necessarily result in such interactions between the molecules of the claimed compounds and, thus, form the claimed molecular complex because such intermolecular interactions are a natural (and innate) property of chemical compounds due to the presence of concentrated electron densities, electron sharing and electron placement within the molecule(s), absent factual evidence to the contrary. Applicant's attempt to establish patentable distinction of the claimed product over that of the prior art by claiming that the two compounds form a "molecular complex" that amounts to no more than intermolecular interactions is not persuasive because the prior art product of Willcox et al. would have been reasonably expected to behave in the same manner and form the same complex (though not expressly recognized by the patentee) in view of the fact that such intermolecular interactions are reasonably expected to naturally occur among compounds containing dipoles and the like, absent any factual evidence to the contrary.

In view of this rationale presented *supra* and also in the previous Office Action that the claimed product and the prior art product are substantially identical and would have inherently formed the claimed "molecular complex", Applicant's mere allegations that the prior art product of Willcox et al. would not have necessarily formed the claimed molecular complex are clearly not persuasive. Applicant has failed to provide any evidence that such a complex would ***not*** form in the composition disclosed by Willcox et al. and has, thus, clearly failed to meet his burden in demonstrating that the products are, in fact, different as required by the MPEP at §2112[R-3](V).

Please see MPEP §2112[R-3](V), which states, "(Once a reference teaching product appearing to be substantially identical is made the basis of a rejection, and the Examiner presents evidence or reasoning tending to show inherency, the burden shifts to Applicant to show an unobvious difference)

'[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, or on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977))." (emphasis added) In view of such guidance, mere allegations, unsupported by factual evidence in the record detailing ***why*** the prior art product would not inherently form this asserted property of a "molecular complex", are clearly insufficient in establishing that the prior art product is different from that presently claimed and, thus, fail to outweigh the evidence of obviousness already in the record.

For these reasons *supra*, and those previously made of record at pages 6-9 of the Office Action dated may 16, 2007, rejection of claims 1-4, 29, 31-34 and 56-57 remains proper and is **maintained**.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Non-Provisional Rejection

Claims 1-4, 29, 31-34 and 56-57 remain rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over, alternatively, claims 28, 35-37 and 41-42 of U.S. Patent No.

5,665,776, or claims 1, 3, 5, and 9 of U.S. Patent No. 5,702,688, or claims 1-4, 38-41 and 51-52 of U.S. Patent No. 5,877,212, each in view of Cole et al. ("A Comparison of a New Oral Antifungal, Terbinafine, With Griseofulvin as Therapy for Tinea Corporis", *Arch Dermatol.* 1989 Nov; 125(11):1537-1539; Abstract Only), each already of record, for the reasons of record set forth at pages 9-12 of the previous Office Action dated May 16, 2007, of which said reasons are herein incorporated by reference.

Newly added claim 56 is properly included in the present rejection because present claim 56 is dependent from claim 1 and further defines that alkaline pharmaceutical drug as terbinafine, which would have been obvious for use in the copending claims for the reasons already of record at page 10 of the previous Office Action.

Newly added claim 57 is also properly included in the present rejection because present claim 57 circumscribes a composition of a molecular complex formed between the same alkaline pharmaceutical drug (i.e., terbinafine) and hydroxyacid (i.e., glycolic acid) as encompassed by claim 1 *et seq*. Regarding the process steps recited in the claim for forming the molecular complex, Applicant is reminded that these limitations are process limitations and fail to materially or structurally limit the claimed complex as a whole. As directed by the MPEP at §2113, "Even though product-by-process claims are limited by and defined by the process, *determination of patentability is based on the product itself.* The patentability of a product does not depend on its method of production. If the product in the product-by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" (see *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985 and MPEP §2113).

In the instant case, though the cited references do not expressly teach the dissolution of the alkaline pharmaceutical drug and an alkali in a suitable reaction medium to form a free base of the pharmaceutical drug, optionally separating the free base of the pharmaceutical drug from the reaction medium and adding at least one of a hydroxyacid, a polyhydroxyacid, a related acid or lactones thereof to

the free base in a suitable reaction medium to form a molecular complex, the copending claims clearly render the instantly claimed composition of a molecular complex between terbinafine and glycolic acid obvious for the reasons previously set forth at pages 9-12 of the prior Office Action.

Applicant traverses the instant rejection, stating that the presence of each component in the composition claims of the cited patents would not necessarily form the molecular complex recited in the instant claims.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

Applicant's allegations that the compositions of the patented claims would not necessarily form the instantly claimed "molecular complex" are unsupported by any factual evidence in the record tending to show that such would, in fact, be the case and are, thus, not persuasive. As set forth in MPEP §2145, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)."

For the reasons *supra*, and those previously made of record at pages 9-12 of the Office Action dated May 16, 2007, rejection of claims 1-4, 29, 31-34 and 56-57 remains proper and is **maintained**.

Provisional Rejection

Claims 1-4, 29-, 31, 33 and 56-57 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending U.S. Patent Application No. 11/050,434 in view of Davis et al. ("Terbinafine. A Pharmacoeconomic Evaluation of Its Use in Superficial Fungal Infections", *Pharmacoeconomics*, 1995 Sep; 8(3):253-269, Abstract Only), already of record, for the reasons of record set forth at pages 12-13 of the Office Action dated May 16, 2007, of which said reasons are herein incorporated by reference.

Newly added claim 56 is properly included in the present rejection because present claim 56 is dependent from claim 1 and further defines that alkaline pharmaceutical drug as terbinafine, which would have been obvious for use in the copending claims for the reasons already of record at page 10 of the previous Office Action.

Newly added claim 57 is also properly included in the present rejection because present claim 57 circumscribes a composition of a molecular complex formed between the same alkaline pharmaceutical drug (i.e., terbinafine) and hydroxyacid (i.e., glycolic acid) as encompassed by claim 1 *et seq.* Regarding the process steps recited in the claim for forming the molecular complex, Applicant is reminded that these limitations are process limitations and fail to materially or structurally limit the claimed complex as a whole. As directed by the MPEP at §2113, "Even though product-by-process claims are limited by and defined by the process, *determination of patentability is based on the product itself.* The patentability of a product does not depend on its method of production. If the product in the product-by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" (see *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985 and MPEP §2113).

In the instant case, though the cited references do not expressly teach the dissolution of the alkaline pharmaceutical drug and an alkali in a suitable reaction medium to form a free base of the pharmaceutical drug, optionally separating the free base of the pharmaceutical drug from the reaction medium and adding at least one of a hydroxyacid, a polyhydroxyacid, a related acid or lactones thereof to the free base in a suitable reaction medium to form a molecular complex, the copending claims clearly render the instantly claimed composition of a molecular complex between terbinafine and glycolic acid obvious for the reasons previously set forth at pages 9-12 of the prior Office Action.

Applicant requests withdrawal of the rejection in view of the fact that all claims are in condition for allowance.

Applicant's request has been fully and carefully considered.

However, in view of the fact that the claims are not in condition for allowance for the reasons *supra*, and further in the absence of any remarks by Applicant regarding the propriety of the rejection or a Terminal Disclaimer, the rejection is hereby **maintained**.

Conclusion

Rejection of claims 1-4, 29, 31-34 and 56-57 is proper and is **maintained**.

Claims 5-28 and 35-55 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

This application contains claims 5-28 and 35-55 drawn to an invention nonelected with traverse in the replies filed on November 27, 2006 and April 16, 2007. **A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

September 22, 2007

Ardin V. Marschel 9/28/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER